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Dan Hardesty

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EXAMINER

HO, ALLEN C

ART UNIT

PAPER NUMBER

2882

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/644,206	Applicant(s) HARDESTY, DAN	
	Examiner Allen C. Ho	Art Unit 2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 10 and 44 are objected to because of the following informalities:

Line 2, "detector circuitry" should be replaced by --detection circuitry--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1 and 35 recite "an x-ray emission system responsive to at least one emission control signal by providing at least first and second doses of x-ray radiation", "an x-ray detection system responsive to at least one detection control signal ... by providing corresponding first and second image signals", and "a control system ... responsive to said first and second image signals by providing said emission and detection control signals". As described in the specification, a first image (33) must be acquired and processed first to produce a control signal (paragraph 21). The specification does not enable one skilled in the art to generate a control

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signal and a detection control signal prior to generating a first image signal because the control system (16) must process a first image to produce control data (161) for the controller (166) to produce appropriate control signals.

Claims 18 and 52 recite "receiving at least one emission control signal". However, claims 18 and 52 later recite "generating, in response to at least said processed first image signal, said emission and detection control signals". Thus, it would not be possible to receive at least one emission control signal prior to processing the first and second volumetric image signals. As described in the specification, a first volumetric image (33) must be acquired and processed first to produce a control signal (paragraph 21). The specification does not enable one skilled in the art to generate a control signal and a detection control signal prior to generating a first image signal because the control system (16) must process a first image to produce control data (161) for the controller (166) to produce appropriate control signals.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2, 5-7, 22-24, 39-41, and 56-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites "said one or more of a plurality of x-ray radiation characteristics comprises at least one of intensity, focal spot and collimation". Since claim 1 claims a sub-portion that is contained at least in part within the portion and the sub-portion does not consist of all of the portion, the x-ray characteristics must comprise at least collimation.

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Claims 5-7, 22-24, 39-41, and 56-58 recite "said subject portion defines a target region". This recitation is indefinite because it is unclear whether the subject portion refers to the portion or the sub-portion recited in claims 1, 18, 35, and 52. Furthermore, it is unclear whether or not the target region refers to the sub-portion recited in claims 1, 18, 35, and 52.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4, 8-10, 14-16, 18-21, 25-28, 31-33, 35-38, 42-44, 48-50, 52-55, 59-62, and 65-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Ning (U. S. Patent No. 6,480,565 B1).

With regard to claims 1 and 35, Ning disclosed an apparatus comprising: an x-ray emission system (210) responsive to at least one emission control signal by providing at least first dose (to acquire scout projection images; column 13, lines 28-59) and second dose (to acquire ultrahigh spatial resolution projections for VOI reconstruction; column 13, line 66 - column 15, line 24) of x-ray radiation, wherein the second dose differs from the first dose in one or more of a plurality of x-ray radiation characteristics (having a different focal spot size and collimated to irradiate only the VOI; column 14, lines 7-37), and the first and second dose are at

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least partially non-contemporaneous; an x-ray detection system (208) responsive to at least one detection control signal and for placement in relation to the x-ray emission system to be responsive to at least a portion of the first and second doses of x-ray radiation following exposure thereto of a portion (breast) of a subject disposed substantially between the x-ray emission and detection systems by providing corresponding first and second image signals, wherein the first and second image signals correspond to the portion and a sub-portion (VOI) of the subject, respectively, and the sub-portion (VOI) is contained at least in part within the portion and does not consist of all of the portion; and a control system (302, 306), coupled to the x-ray emission and detection systems, responsive to at least the first image signal by providing the emission control signal (focal spot size and collimation; column 13, line 66 - column 14, line 37) and the detection control signal (detector resolution in the zoom mode; column 13, line 66 - column 14, line 37), wherein, in relation to a portion of the first image signal corresponding to the sub-portion of the subject, the second image signal differs from the first image signal in one or more of a plurality of image characteristics.

With regard to claims 2-4 and 36-38, Ning disclosed the apparatus of claims 1 and 35, wherein: the x-ray emission system comprises a collimator (502); the one or more of a plurality of x-ray radiation characteristics comprises at least one of intensity, focal spot (column 13, line 66 - column 14, line 37), and collimation (column 15, lines 1-24); and the one or more of a plurality of image characteristics comprises image resolution (column 13, line 66 - column 14, line 37).

With regard to claims 8 and 42, Ning disclosed the apparatus of claims 1 and 35, wherein the x-ray emission system comprises: an x-ray source (210) responsive to a first portion of the at

least one emission control signal by providing x-ray radiation with at least one of the plurality of x-ray radiation characteristics corresponding to the first portion of the at least one emission control signal; and a collimator (502) coupled to the x-ray source and responsive to a second portion of the at least one emission control signal by conveying the x-ray radiation with at least another of the plurality of x-ray radiation characteristics corresponding to the second portion of the at least one emission control signal.

With regard to claims 9 and 43, Ning disclosed the apparatus of claims 1 and 35, wherein the x-ray detection system comprises detection circuitry (312) responsive to a first portion of the at least one detection control signal and the respective portions of the first and second doses of x-ray radiation by providing a plurality of pixel signals.

With regard to claims 10 and 44, Ning disclosed the apparatus of claims 9 and 43, wherein the x-ray detection system further comprises processing circuitry (336) coupled to the detector circuitry and responsive to a second portion of the at least one detection control signal and the plurality of pixel signals by providing the first and second image signals.

With regard to claims 14, 15, 48, and 49, Ning disclosed the apparatus of claims 1 and 35, wherein the at least one emission control signal comprises at least one signal for controlling at least one of a plurality of operating parameters for the x-ray emission system, wherein the at least one of a plurality of operating parameters for the x-ray emission system comprises at least one of a voltage, a current, a focal spot, and collimation (column 14, lines 7-37).

With regard to claims 16 and 50, Ning disclosed the apparatus of claims 1 and 35, wherein the at least one detection control signal comprises at least one signal for controlling at

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least one of a plurality of operating parameters for the x-ray detection system (column 14, lines 7-37).

With regard to claims 18 and 52, Ning disclosed an automated method for producing a plurality of x-ray image signals corresponding to selected views of a subject with selectively variable image resolutions, the method comprises: receiving at least one emission control signal; generating (210), in response to the at least one emission control signal, at least first dose (to acquire scout projection images; column 13, lines 28-59) and second dose (to acquire ultrahigh spatial resolution projections for VOI reconstruction; column 13, line 66 - column 15, line 24) of x-ray radiation, wherein the second dose differs from the first dose in one or more of a plurality of x-ray radiation characteristics (having a different focal spot size and collimated to irradiate only the VOI; column 14, lines 7-37), and the first and second doses are at least partially non-contemporaneous; receiving (208) at least a portion of the first and second doses of x-ray radiation following exposure thereto of a portion (breast) of a subject; receiving at least one detection control signal; generating, in response to the at least one detection control signal and the at least a portion of the first and second doses of x-ray radiation, first and second image signals, wherein the first and second image signals correspond to the portion and a sub-portion (VOI) of the subject, respectively, and the sub-portion is contained at least in part within the portion and does not consist of all of the portion; processing (336) the first and second image signals; and generating, in response to at least the processed first image signal (column 14, lines 47-57), the emission and detection control signals, wherein, in relation to a portion of the first image signal corresponding to the sub-portion of the subject, the second image signal differs

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from the first image signal in one or more of a plurality of image characteristics (column 14, lines 7-37).

With regard to claims 19-21 and 53-55, Ning disclosed the method of claims 18 and 52, wherein: the generating, in response to the at least one emission control signal, at least first and second doses of x-ray radiation comprises controlling a collimator (502); the one or more of a plurality of x-ray radiation characteristics comprises focal spot and collimation (column 14, lines 7-37); and the one or more of a plurality of image characteristics comprises image resolution (column 14, lines 7-37).

With regard to claims 25 and 59, Ning disclosed the method of claims 18 and 52, wherein the generating, in response to the at least one emission control signal, at least first and second doses of x-ray radiation comprises: collimating, in response to a second portion of the at least one emission control signal, the x-ray radiation (column 15, lines 1-24).

With regard to claims 26 and 60, Ning disclosed the method of claims 25 and 59, wherein the generating, in response to the at least one detection control signal and the at least a portion of the first and second doses of x-ray radiation, first and second image signals comprises generating, in response to a first portion of the at least one detection control signal, a plurality of pixel signals (column 14, lines 7-37).

With regard to claims 27 and 61, Ning disclosed the method of claims 26 and 60, wherein the generating, in response to the at least one detection control signal and the at least a portion of the first and second doses of x-ray radiation, first and second image signals further comprises processing the plurality of the pixels signals to generate the first and second image signals (column 9, line 7 - column 10, line 5).

With regard to claims 28 and 62, Ning disclosed the method of claims 18 and 52, wherein the generating, in response to the processed first and second image signals, the emission and detection control signals comprises storing a plurality of image data corresponding to the first and second image signals (column 9, lines 7-28).

With regard to claims 31, 32, 65, and 66, Ning disclosed the method of claims 18 and 52, wherein the generating, in response to the processed first and second image signals, the emission and detection control signals comprises generating at least one signal for controlling at least one of a plurality of parameters for the generating of the at least first and second doses of x-ray radiation, wherein the at least one of a plurality of parameters comprises at least a focal spot and collimation (column 14, lines 7-37).

With regard to claims 33 and 67, Ning disclosed the method of claims 18 and 52, wherein the generating, in response to the processed first and second image signals, the emission and detection control signals comprises generating at least one signal for controlling at least one of a plurality of parameters for the generating of the first and second image signals (column 14, lines 7-37).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 5-7, 22-24, 39-41, and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ning (U. S. Patent No. 6,480,565 B1) as applied to claims 1, 18, 35, and 52 above, and further in view of Shinno *et al.* U. S. Patent No. 7,085,343 B2).

With regard to claims 5-7, 22-24, 39-41, and 56-58, Ning disclosed the apparatus of claims 1 and 35 and method of claims 18 and 52. However, Ning failed to disclose an x-ray emission system that is responsive to the at least one emission control signal by controlling a first spatial relation to the sub-portion and an x-ray detection system that is responsive to the at least one detection control signal by controlling a second spatial relation to the sub-portion.

Shinno *et al.* disclosed an apparatus that comprises an x-ray emission system (3121), an x-ray detection system (3123), and a collimator (3122). A region of interest is identified in a low-resolution tomographic image. Subsequently, the region of interest (ROI) is positioned on the rotation axis (RA) by controlling a position of a table. Shinno *et al.* taught that the position of the collimator is fixed when the region of interest is positioned on the rotation axis (column 20, lines 50-62).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a mechanism to control the first spatial relation and the second spatial relation, since a person would be motivated to fix the position of the collimator by positioning the sub-portion on the rotation axis. Otherwise, the position of the collimator must be constantly adjusted, which leads to additional complexities.

10. Claims 17, 34, 51, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ning (U. S. Patent No. 6,480,565 B1) as applied to claims 16, 33, 50, and 67 above, and further in view of Nambu *et al.* (U. S. Patent No. 6,196,715 B1).

With regard to claims 17, 34, 51, and 68, Ning disclosed the apparatus of claims 16 and 50 and method of claims 33 and 67. However, Ning failed to teach that the at least at least one of the plurality of operating parameters for the x-ray detection system comprises at least one of bias and dynamic range.

Nambu *et al.* disclosed an x-ray detection system, whose dynamic range is controlled in accordance with pixel values of projection data to avoid overflow (column 22, lines 15-21)

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a detection control signal for controlling the dynamic range of the x-ray detection system, since a person would be motivated to set a dynamic range that is appropriate for the volumetric image signals.

11. Claims 11-13, 29, 30, 45-47, 63, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ning (U. S. Patent No. 6,480,565 B1) as applied to claims 1, 28, 35, and 62 above, and further in view of Giger *et al.* (U. S. Patent No. 6,901,156 B2).

With regard to claims 11-13 and 45-47, Ning disclosed the apparatus of claims 1 and 35, wherein the control system comprises: receiving circuitry (332, 334) responsive to the first and second image signals by storing a corresponding plurality of image data.

However, Ning failed to disclose a processing circuitry, coupled to the receiving circuitry, to selectively process the plurality of stored image data and a plurality of reference data and in response thereto provide a plurality of control data.

Giger *et al.* disclosed a processing circuitry that process a plurality of stored image data (102) and a plurality of reference data (112) to confirm diagnosis of a pathological state (column 5, lines 8-10).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a processing circuitry, coupled to the receiving circuitry, to selectively process the plurality of stored image data and a plurality of reference data and in response thereto provide a plurality of control data, since a person would be motivated to determine whether or not a sub-portion is malignant.

With regard to claims 29, 30, 63, and 64, Ning disclosed the method of claims 28 and 62. However, Ning failed to disclose processing the plurality of stored image data and a plurality of reference data and in response thereto generating a plurality of control data.

Giger *et al.* disclosed a method of determining a pathological state of a sub-portion in an image that comprises comparing the sub-portion of the image with a reference database (112).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to process the plurality of stored image data and a plurality of reference data and in response thereto generating a plurality of control data, since a person would be motivated to determine whether or not a sub-portion is malignant.

Response to Arguments

12. Applicant's arguments filed 15 September 2006 with respect to claims 2, 4, 19, 21, 36, 38, 53, and 55 have been fully considered and are persuasive. The rejection of claims 2, 4, 19, 21, 36, 38, 53, and 55 under 35 U.S.C. 112, second paragraph, has been withdrawn.

13. Applicant's arguments filed 15 September 2006 with respect to the rejection(s) of claim(s) 1-68 under 35 U.S.C. 102(e) have been fully considered and are persuasive. Therefore,

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the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Ning (U. S. Patent No. 6,480,565 B1).

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- (1) Marcovitch (U. S. Pub. No. 2006/0140339 A1) disclosed a dual function CT scan.
- (2) Popescu (U. S. Patent No. 6,501,828 B1) disclosed a method and an apparatus that collimates a region of interest.
- (3) Gilhuijs *et al.* (U. S. Patent No. 6,317,617 B1) disclosed a method that compares images from different modalities to conform a pathological state of a tumor (column 14, lines 6-25).


Note: References (1) and (2) have been applied to a copending application 10/907,747.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allen C. Ho whose telephone number is (571) 272-2491. The examiner can normally be reached on Monday - Friday from 8:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward J. Glick can be reached on (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Allen C. Ho, Ph.D.
Primary Examiner
Art Unit 2882

11 December 2006